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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : Sandberg et al. Examiner : M. Borin
Application No. : 09/580,156 Group Art : 1631
Filing Date : May 30, 2000
Title : ELASTIN PEPTIDE ANALOGS AND USES THEREOF
Docket No. : 99-489-US-P (old)
25812-5-CIP (new)

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Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT AND SPECIES REQUIREMENT

Dear Sir:

In response to the Restriction Requirement dated October 3, 2001, Applicant provisionally elects, with traverse, the designated invention of Group I (Claims 1 through 11, 13, 19, 20 (all in part)), drawn to elastin fragments of SEQ ID Nos. 1-48 and compositions thereof. In response to the Species Requirement of same date, Applicant provisionally elects, with traverse, the disclosed species in Sequence Number 48, namely Glycine-Alanine-Valine-Valine-Proline-Glutamine-amide. A copy of the Restriction Requirement and Species Requirement is enclosed for the Examiner's convenience.

The Restriction Requirement set a shortened statutory period for response of one month to expire November 3, 2001. Because this Response to Restriction Requirement is being filed on November 2, 2001 with a proper Certificate of Mailing, this Response is timely filed without extension.



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In re application of : Lawrence B. Sandberg et al.
Serial No. : 09/580,156 Art Unit: 1631
Filing Date : May 30, 2000
Docket No. : 25812-5-CIP
Title : ELASTIN PEPTIDE ANALOGS AND USES THEREOF

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8*

I hereby certify that these papers is being deposited with the United States Postal Service with sufficient postage as "FIRST CLASS MAIL" in an envelope addressed to: Commissioner for Patents, Washington , D.C. 20231.

November 2, 2001
(Date)

Ondrea Saffo
(type or print name of person mailing paper)

Ondrea Saffo
Signature

Documents Enclosed:

1. Response to Restriction Requirement and Species Requirement.
2. Copy of Restriction Requirement and Species Requirement dated October 3, 2001.
3. A self-addressed, stamped postcard, return of which is requested to acknowledge receipt of the Response.



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/580,156 05/30/00 SANDBERG

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25812-5-CIP
57-489-US-P

EXAMINER

HM12/1003

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BORIN, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

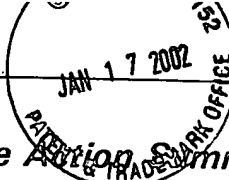
10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary



Application No.

09/580,156

Applicant

Sandberg et al.

Examiner

Michael Borin

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Art Unit: 1631

Part III DETAILED ACTION

Claims 1-20 are pending.

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 13, 19, 20 (all in part), drawn to elastin fragments of SEQ ID Nos.: 1-48 and compositions thereof, classified in class 514, subclasses 15-18, and class 530, subclasses 328-330.
- II. Claims 1-11, 13, 19, 20 (all in part), as drawn to compositions comprising cyclic peptides (SEQ ID Nos: 48-51), classified in class 514, subclass 9.
- III. Claims 1-11 (all in part), as drawn to compositions comprising copper salts of peptides (SEQ ID No.52-54), classified in class 514, subclass 6.
- IV. Claims 15-18(all in part), drawn to method of enhancing tissue elasticity using elastin fragments, classified in class 514, subclasses 15, 16.
- V. Claims 15-18 (all in part), as drawn to method of enhancing tissue elasticity using cyclic peptides (SEQ ID Nos:48-51), classified in class 514, subclass 9.
- VI. Claims 15-18 (all in part), as drawn to method of enhancing tissue elasticity copper salts of peptides (SEQ ID No. 52-54), classified in class 514, subclass 6.

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VII. Claims 12, 14, drawn to peptide of general formula of claim 12, classified in class 530, subclass 330.

The inventions are distinct, each from the other because of the following reasons:

The linear peptides, copper salts and cyclic peptides of Groups I-III are drawn to independent and/or patentably distinct compounds since each of these compounds possess different structure (e.g., primary, secondary and tertiary structure) and/or physico-chemical properties, and/or capable of separate manufacture and/or use. The correspondent methods of use IV-VI are independent and/or distinct due to the use of different patentably distinct agents.

Inventions I-III and IV-VI are related as products and respective processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used in a materially different processes such as peptide synthesis or in pharmaceutical formulations. Further, the method as claimed can be used with other products, such as elastin.

Inventions I and VII are patentably distinct from each other because of the materially different structures of the compounds they are claiming. The scope of the genus of claims 12, 14 is different from the selection of particular peptides of Group I. The genus of Group VII does not include all peptides of Group I (e.g., tripeptides). It is noted that Groups I and VII share certain

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species (of claim 13; the latter is assigned to Group I). If the common species, Groups I and VII will be examined together to the extent they read on elected species.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

Upon election of any single one of the Groups from above the following election of species is hereby required:

Species Requirement

Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims.(MPEP 808.01(a))

Upon election of any single one of the Groups from above the following election of species is hereby required for the initial search for examination on merits:

The claims of the Group are individually or dependently directed to a plurality of disclosed patentably distinct species of peptides which are not a result of conservative substitutions of amino acid residues. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, such as those in claim 1, 13 or 15.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds

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one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

September 26, 2001

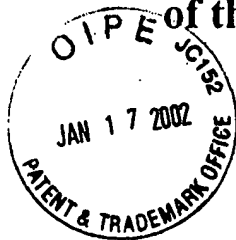
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Attachment for PTO-948 (Rev. 03/01, or earlier)

6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.



INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

06/01/01